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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,543	09/23/2003	Michael P. Wallace	03-398 (US01)	4647

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VISTA IP LAW GROUP LLP
12930 Saratoga Avenue
Suite D-2
Saratoga, CA 95070

EXAMINER	
YABUT, DIANE D	
ART UNIT	PAPER NUMBER
3734	
MAIL DATE	DELIVERY MODE
02/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,543	WALLACE, MICHAEL P.	
	Examiner	Art Unit	
	Diane Yabut	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,10,11 and 13-22* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10,11 and 13-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/29/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/2007 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 10/29/2007 is considered. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 8 is objected to because of the following informalities: Claim 8 reads “The method of claim 7,” however claim 7 is currently cancelled and therefore claim 8 must be dependent on an existing claim. Therefore, claim 8 has not been further treated on the merits thereof.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-2, 6, 19, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lee** (U.S. Patent No. **6,397,107**) in view of **Engelson** (U.S. Patent No. **5,749,894**).

Claims 1-2, 6, 19, and 22: Lee discloses detaching a vaso-occlusive device ("coil") **3** from a delivery catheter **1** to thereby deploy the vaso-occlusive device at a target site in a vasculature of a body including an aneurysm, and delivering energy from an energy emitting element ("induction coil") **13** located outside the body to thereby heat the vaso-occlusive device at the target site (Figures 1-2 and col. 2, lines 50-65).

Lee does not expressly disclose the vaso-occlusive device comprising a bioactive agent, wherein the bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated, wherein the energy-emitting element is a radio frequency device.

Engelson teaches a vaso-occlusive device comprising a bioactive agent ("polymeric material"), wherein the bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated, wherein the energy-emitting element is a radio frequency device (see abstract; col.1, lines 4-17, col. 4, lines 11 to col. 5, line 64, and col. 6, lines 1-10). The delivered heating energy causes a coating on

the vaso-occlusive device to at least partially melt or soften, thereby releasing the bioactive agent (col. 9, lines 20-37)

It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bioactive agent in the vaso-occlusive device heated by radio frequency energy, as taught by Engelson, to Lee since it was well known in the art to use agents for endovascular therapy that act as the glue or a means for making the vas-occlusive device self-adherent, as well to use radio frequency energy as an energy-emitting element.

6. Claims 3-4, 10, 13, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lee** (U.S. Patent No. **6,397,107**) and **Engelson** (U.S. Patent No. **5,749,894**), as applied to claim 1 above, and further in view of **Yamasaki** (U.S. Pub. No. **2004/0215124**).

Claims 3, 10, and 13: Lee and Engelson disclose the claimed invention except for the energy-emitting element comprising a magnetic resonance device, positioning the body in a magnetic resonance imaging ("MRI") device, and activating the MRI device to apply a variable magnetic field to the body.

Yamasaki teaches a method and apparatus for aneurismal treatment using a heating source or energy-emitting element comprising a magnetic resonance device (page 7, paragraph 88). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the energy-emitting element outside the body in Lee by providing a magnetic resonance device, as taught by Yamasaki, since it was known in

the art that an MRI source yields higher temperature to effectively heat materials that are commonly used in vaso-occlusive devices that absorb MRI and radiofrequency energy.

Yamasaki also teaches positioning the body in a magnetic resonance imaging ("MRI") device and activating the MRI device to apply a variable magnetic field to the body, which would thereby heat a highly resistive element in the vaso-occlusive device (page 7, paragraph 88). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a magnetic resonance device as a source, as taught by Yamasaki, to Lee and Engelson since it was known in the art that an MRI source yields higher temperature to effectively heat materials that are commonly used in vaso-occlusive devices that absorb MRI and radiofrequency energy.

Claims 4 and 20: Lee and Engelson disclose the claimed invention except for the vaso-occlusive device comprising a ferrous material in sufficient concentration to cause heating of the device in response to energy delivered by the magnetic resonance device.

Yamasaki teaches a ferrous material ("magnetically responsive particles Fe_3O_4") in sufficient concentration to cause heating of the device in response to energy delivered by the magnetic resonance device (page 1, paragraph 6). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a vaso-occlusion device comprising a ferrous material that responds to applied energy so that the device remains cohesive (page 1, paragraph 5) and therefore properly treating the target site.

7. Claims 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lee** (U.S. Patent No. **6,397,107**) and **Engelson** (U.S. Patent No. **5,749,894**), as applied to claims 1 and 19 above, and further in view of **Maitland** (U.S. Patent No. **6,740,094**).

Claims 5 and 21: Lee and Engelson disclose the claimed invention except for the energy-emitting element comprising an ultrasound device acoustically coupled to an exterior of the body.

Maitland teaches a source comprising an ultrasound device acoustically coupled to an exterior of a body, which allows for both local and remote heating (col. 6, lines 26-57). I It would have been obvious to one of ordinary skill in the art at the time of invention to modify the energy-emitting element outside the body in Lee by providing an ultrasound device source, as taught by Maitland, to Engelson in order to allow for both local or remote heating and since it was known in the art that acoustic/ultrasound waves effectively heat materials that are commonly used in vaso-occlusive devices that absorb ultrasonic energy.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Lee** (U.S. Patent No. **6,397,107**), **Engelson** (U.S. Patent No. **5,749,894**), and **Yamasaki**, as applied to claim 10 above, and further in view of **Lennox** (U.S. Patent No. **5,405,322**).

Claim 11: Lee, Engelson, and Yamasaki disclose the claimed invention including being heated by application of magnetic field energy, except for being sufficiently heated to cause coagulation of blood at the target site.

Lennox teaches a method for treating aneurysms using a thermal source for a body to be sufficiently heated to cause coagulation of blood at the target site in order to form fibrous scar tissue in the weakened aneurysm wall and reduces compliance and arrest aneurysm formation (col. 4, lines 13-25). It would have been obvious to one of ordinary skill in the art at the time of invention to provide heat to cause coagulation of blood at the target site, as taught by Lennox, to Lee, Engelson, and Yamasaki in order to form fibrous scar tissue in the weakened aneurysm wall and reduces compliance and arrest aneurysm formation.

9. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lee** (U.S. Patent No. **6,397,107**) in view of **Yamasaki** (U.S. Pub. No. **2004/0215124**). Claims 14-15: Lee discloses the claimed invention, including detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device in an aneurysm and applying magnetic field energy to the device from an energy-emitting element located outside of the body, and a highly conductive metallic coil **3** that interacts with a magnetic field to form an eddy current (see paragraph 5 above), but does not disclose a highly resistive element comprising a ferrous material at least partially disposed in the lumen which is heated by way of convective heat transfer from the highly resistive element.

Yamasaki teaches a highly resistive ferrous material ("magnetically responsive particles Fe_3O_4") in sufficient concentration to cause heating of the device in response to energy delivered by the magnetic resonance device (page 1, paragraph 6). It would

have been obvious to one of ordinary skill in the art at the time of invention to provide a resistive element within the coil of Lee in order for the material to respond to applied energy so that the device remains cohesive (page 1, paragraph 5) and to therefore properly treat the target site.

Response to Arguments

10. Applicant's arguments with respect to claims 1-6, 8, 10-11, and 13-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734
/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731